

Application No.: 10/564,125
Filing Date: August 21, 2006

REMARKS

After entry of the present amendments, Claims 1-3, 8-27, 32, and 34 will be pending. Claims 1, 32, and 34 are amended herein. Claims 4-7, 29, 31, and 33 are canceled herein.

Claim 1 is amended to recite that the kappa-casein containing milk protein is an ultrafiltration retentate and that the divalent ion content is adjusted by cation exchange using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium. Claim 32 is amended to indicate that milk is subject to ultrafiltration. The dependency of Claim 34 is adjusted in view of the cancellation of Claim 33. Support for the amendments can be found throughout the claims and specification as filed. No new matter is added.

Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

Rejections under 35 U.S.C. § 101

The Examiner rejected Claims 29 and 31 under 35 U.S.C. § 101, because the claimed invention is directed to non-statutory subject matter. Without acquiescing in the rejection, Claims 29 and 31 are canceled herein, thereby obviating this rejection.

Legal Standards for Anticipation

Anticipation under Section 102 can be found only if a reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). More particularly, a finding of anticipation requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994).

Applicants also note that "[i]nherency, however, may not be established by probabilities or possibilities. The fact that a given thing *may* result from a given set of circumstances is not sufficient." *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). *See also Tintec Industries, Inc. v. Top-USA Corp.*, 63 U.S.P.Q.2d 1597, 1599 (Fed. Cir. 2002). When relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the

teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d. 1461, 1464 (Bd. Pat. App. & Inter. 1990)(emphasis added).

Legal Standards for Obviousness

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); (“the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]”, *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)); *see also M.P.E.P. § 2143.03*. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

General Foods Fails to Anticipate Claims 1-4, 8-27, and 32-34

Claims 1-4, 8-27, 32-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by EP 0435573 to General Foods (hereinafter “General Foods”).

Without acquiescing in the rejection, Claim 1 is amended herein to recite in part “adjusting the divalent ion content of said protein solution to a predetermined level at which no substantial gel is formed after treatment with a milk clotting enzyme wherein said adjusting is achieved by cation exchange using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium”.

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General Foods fails to disclose this feature because General foods only discloses ultrafiltration or diafiltration to lower the concentration of all minerals (e.g. both cations and anions) without any replacement. See whole document, in particular Examples I and II.

Further, General Foods only discloses mechanical agitation to avoid coagulation. ("it has been determined that the retentate can be maintained in a fluid state without formation of a coagulum during the fermentation step if the retentate is subjected to total movement during fermentation to prevent coagulum." Col. 7, ll. 17-22, emphasis added). There is no recognition in General Foods of any other way to avoid formation of a coagulum and no reason to replace one type of cation with another.

Coagulation formation in the claimed processes is avoided by reducing the divalent ion content of the protein solution instead of the mechanical agitation of General Foods. Thus, General Foods fails to disclose the features of Claim 1. Accordingly, Applicants respectfully request withdrawal of Claim 1 and its dependents.

Additionally, this feature is more than an obvious variation because there is no reason to use cation exchange as claimed in Claim 1 in the process of General Foods as there is no recognition in General Foods of any other way to avoid formation of a coagulum and no reason to replace one type of cation with another.

Additionally, Applicants submit that Claims 2-3, 8-27, 32, and 34 are not anticipated by General Foods, not only because they depend from Claim 1 but also on their own merit.

Schreiber Foods Fails to Anticipate Claims 1-4, 6-27, and 32-34

Claims 1-4, 6-27, 32-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by WO 82/01806 to Schreiber Foods (hereinafter "Schreiber Foods").

Without acquiescing in the rejection, Claim 1 is amended herein to recite in part "adjusting the divalent ion content of said protein solution to a predetermined level at which no substantial gel is formed after treatment with a milk clotting enzyme wherein said adjusting is achieved by cation exchange using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium".

Schreiber Foods fails to disclose cation exchange as recited in Claim 1. Schreiber Foods discloses diafiltration and ultrafiltration, which removes both cations and anions. See page 16,

line 24 to page 18, line 29. Schreiber Foods then discloses adjusting the ionic strength of the retentate using sodium chloride. See page 19, lines 9-26. Thus, Schreiber Foods fails to disclose cation exchange using a food grade cation exchanger as claimed in Claim 1. Accordingly, Applicants respectfully request withdrawal of this rejection of Claim 1.

Additionally, this feature is more than an obvious variation because there is no reason to use cation exchange as claimed in Claim 1 in the process of Schreiber. Schreiber avoids coagulation through the use of high ionic strength (see abstract).

Additionally, Applicants submit that Claims 2-3, 8-27, 32, and 34 are not anticipated by Schreiber Foods, not only because they depend from Claim 1 but also on their own merit.

Bhaskar Fails to Anticipate or Make Obvious Claims 1-27 and 32-34

Claims 1-27 and 32-34 stand rejected under 35 U.S.C. § 102 as anticipated or in the alternative under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Patent Publication No. 2003-0096036 to Bhaskar et al. (hereinafter “Bhaskar”). Claims 2-27 and 32-34 depend from Claim 1.

Applicants note that the Examiner has only generally alleged that Bhaskar discloses the features of independent Claim 1. The Examiner has failed to particularly point out how Bhaskar discloses any of the features of the claims, and has not provided any citations to the relevant sections of Bhaskar. Nevertheless, Applicants have attempted to address the Examiner’s concerns.

Applicants note that Bhaskar is concerned with the formation of calcium depleted dried milk protein concentrate (MPC) and its subsequent use to manufacture cheese.

Bhaskar fails to disclose “adding a food grade milk clotting enzyme under reaction conditions appropriate to convert said kappa-casein to para kappa-casein *while maintaining a solution*”. The methods for manufacturing MPC do not disclose this feature. See Figure 1.

Bhaskar discloses reconstituting calcium depleted milk to form substantially nugget free cheese by standard cheddaring methods. See paragraph [0076]. Making cheese with the reconstituted MPC does not anticipate or suggest the process as claimed. For example, Bhaskar discloses the use of rennet *to form a coagulum* as part of the standard cheddar process. Paragraphs [0079] and [0104] (“All preparations developed a coagulum at 40 minutes after

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rennet was added”). Thus, Bhaskar fails to disclose “adding a food grade milk clotting enzyme under reaction conditions appropriate to convert said kappa-casein to para kappa-casein *while maintaining a solution*” as claimed in Claim 1 and fails to provide a reason to do so. Accordingly, Applicants request withdrawal of the anticipation and obviousness rejections for at least this reason.

Additionally, Bhaskar fails to disclose “concentrating said solution” after deactivating or removing said enzyme, as recited in Claim 1 because there is no concentration step after the formation of curds and whey in the process of Bhaskar. Applicants request withdrawal of the anticipation and obviousness rejections for at least this reason as well.

Further, the Examiner has not shown that any of the features of the pending claims are inherently present in Bhaskar. This is especially true because there are no specific citations to Bhaskar in the Office Action.

There is also no reason to modify Bhaskar to perform the steps recited in Claim 1. Bhaskar describes preparing an MPC ingredient without the use of clotting enzymes and only uses rennet to produce curd in a cheese making process, not to produce a solution comprising para kappa-casein that can be subsequently concentrated.

There is also no reasonable expectation of success to arrive at the features of Claim 1. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. As discussed above, Bhaskar fails provide any teaching that would suggest to one of skill in the art that it would be possible to adjust the divalent ion content of said protein solution to a predetermined level at which no substantial gel is formed after treatment with a milk clotting enzyme. Further, since they are trying to coagulate to make cheese Bhaskar actually teaches away from this feature. Accordingly, the skilled artisan would have no reasonable expectation of success. Thus, Applicants respectfully request withdrawal of the rejection for at least this reason.

Additionally, Applicants submit that Claims 27 and 32-34, are not made obvious or anticipated by Bhaskar, not only because they depend from Claim 1 but also on their own merit.

Poarch Fails to Anticipate or Make Obvious Claims 1-19 and 22

Claims 1-19 and 22 stand rejected under 35 U.S.C. § 102 as anticipated or in the alternative under 35 U.S.C. § 103(a) as unpatentable in view of U.S. Patent No. 4,202,907. Claims 2-19 and 22 depend from Claim 1. Poarch generally discloses the use of modified milk products for use as additives in sausage.

Claim 1 is amended herein to recite in part “providing a solution having a kappa-casein containing milk protein which is an ultrafiltration retentate”. Poarch fails to disclose the use of ultrafiltration. In contrast, Poarch discloses starting with fresh or reconstituted skim milk and passing it through an ion exchange material. *See* Milk Product Preparation section, col. 6 line 23 to col. 9, line 45. Accordingly, Poarch fails to disclose the features of Claim 1.

This is also more than an obvious variation of the disclosure of Poarch because using ultrafiltration would produce a product that is not suitable for Poarch’s process. Poarch discloses that “[t]he special gels of this invention are ‘brittle’ in nature as opposed to the elastic or rubbery and plastic texture of the regular gels. This is of particular significance in the manufacture of firm but still succulent meat products such as frankfurters and meatballs and when the described product is a component of canned meat spreads.” Col. 4, ll. 26-28 (emphasis added).

Poarch further teaches away from using the claimed process because Poarch is concerned with brittle gels and says that regular gels are problematic, finding that regular gels are unsuitable for the use as a meat additive. In particular Poarch discloses:

On the other hand, the regular gels, or highly viscous solutions that resemble gels such as result from the use of gelatins, gums, concentrated protein and the like in sausage, more or less retain their elastic, plastic or rubbery characteristics at lower temperatures but become sticky solutions when the sausage is heated to eating temperatures and either are inclined to interfere with the succulence of the sausage or leave a coated sensation on the tongue. Col. 4, ll. 42-50.

Poarch is concerned with forming a brittle gel, in contrast to the product prepared by the claimed methods for use in the production of cheese and cheese type products. *See* Example 6 of the specification. The skilled artisan would expect ultrafiltration to reduce the lactose content of the starting material thereby resulting in an elastic product.

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Thus, the process as claimed would produce a product that would frustrate the purpose of Poarch and produce a meat product with an unacceptable texture. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP § 2143.01. Accordingly, Poarch wouldn't start with an ultrafiltration retentate. Applicants respectfully request withdrawal of this rejection for at least this reason as well.

For the reasons discussed above the skilled artisan would not have a reasonable expectation of success to use the recited process to prepare a meat additive for the process of Poarch. Poarch uses brittle gels and the skilled artisan would not expect a process that creates elastic gels to work – Poarch explicitly says so. Accordingly, Applicants respectfully request withdrawal of this rejection for at least this reason as well.

Thus, there is no reason to modify the disclosure of Poarch to perform the claimed features or suggestion that the modified milk product of Poarch could be used to make a cheese or cheese type product. Thus, Applicants respectfully request withdrawal of this rejection for at least this reason.

Additionally, Applicants submit that Claims 2-3, 8-19 and 22, are not made obvious or anticipated by Poarch, not only because they depend from Claim 1 but also on their own merit.

No Disclaimers or Disavowals

Although the present communication includes alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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